(Rel 88—10/01 Pub 605) FORM 13-18 13-159

JC07 Rec'd PCT/PTO 23 JAN 2002

Practitioner's Docket No. HMN 2 0021

CHAPTER II

Preliminary Classification:

Proposed Class:

Subclass:

NOTE: "All applicants are requested to include a preliminary classification on newly filed patent applications. The preliminary classification, preferably class and subclass designations, should be identified in the upper right-hand corner of the letter of transmittal accompanying the application papers, for example 'Proposed Class 2, subclass 129.'" M.P.E.P., § 601, 7th ed.

TRANSMITTAL LETTER TO THE UNITED STATES ELECTED OFFICE (EO/US) (ENTRY INTO U.S. NATIONAL PHASE UNDER CHAPTER II)

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/EP00/06997	21 July 2000 (21.07.2000)	23 July 1999 (23.07.1999)

TITLE OF INVENTION: USE OF TOSYLCHLORAMIDE(S) FOR TREATING DISEASES OF THE SKIN, MUCOUS MEMBRANES, ORGANS AND TISSUES

APPLICANT(S): RAPP, Horst and HECK, Friedbert

Box PCT
Assistant Commissioner for Patents
Washington D.C. 20231
ATTENTION: EO/US

CERTIFICATION UNDER 37 C.F.R. §§ 1.8(a) and 1.10*
(When using Express Mail, the Express Mail label number is mandatory; Express Mail certification is optional.)

I hereby certify that, on the date shown below, this correspondence is being:

MAILING

☒ deposited with the United States Postal Service in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231

37 C.F.R. § 1.8(a)

☐ with sufficient postage as first class mail.

37 C.F.R. § 1.10 *

☒ as "Express Mail Post Office to Addressee" Mailing Label No. EV 020233684 US (mandatory)

TRANSMISSION

☐ facsimile transmitted to the Patent and Trademark Office, (703) _____-_____.

Georgeen B George
Signature

Date: 1/23/02

Georgeen B. George
(type or print name of person certifying)

** Only the date of filing (§ 1.6) will be the date used in a patent term adjustment calculation, although the date on any certificate of mailing or transmission under § 1.8 continues to be taken into account in determining timeliness. See § 1.703(f). Consider "Express Mail Post Office to Addressee" (§ 1.10) or facsimile transmission (§ 1.6(d)) for the reply to be accorded the earliest possible filing date for patent term adjustment calculations.*

NOTE: To avoid abandonment of the application, the applicant shall furnish to the USPTO, not later than 20 months from the priority date: (1) a copy of the international application, unless it has been previously communicated by the International Bureau or unless it was originally filed in the USPTO; and (2) the basic national fee (see 37 C.F.R. § 1.492(a)). The 30-month time limit may not be extended. 37 C.F.R. § 1.495.

***WARNING:** Where the items are those which can be submitted to complete the entry of the international application into the national phase are subsequent to 30 months from the priority date the application is still considered to be in the international state and if mailing procedures are utilized to obtain a date the express mail procedure of 37 C.F.R. § 1.10 must be used (since international application papers are not covered by an ordinary certificate of mailing—See 37 C.F.R. § 1.8*

NOTE: Documents and fees must be clearly identified as a submission to enter the national state under 35 U.S.C. § 371 otherwise the submission will be considered as being made under 35 U.S.C. § 111. 37 C.F.R. § 1.494(f).

I. Applicant herewith submits to the United States Elected Office (EO/US) the following items under 35 U.S.C. § 371:

a. ☒ This express request to immediately begin national examination procedures (35 U.S.C. § 371(f)).

b. ☐ The U.S. National Fee (35 U.S.C. § 371(c)(1)) and other fees (37 C.F.R. § 1.492) as indicated below:

2. Fees

CLAIMS FEE	(1) FOR	(2) NUMBER FILED	(3) NUMBER EXTRA	(4) RATE	(5) CALCULATIONS
☒*	TOTAL CLAIMS	16 −20=	0	× $18.00=	$ 0
	INDEPENDENT CLAIMS	1 −3=	0	× $84.00=	0
	MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ $280.00	
BASIC FEE**	☐ U.S. PTO WAS INTERNATIONAL PRELIMINARY EXAMINATION AUTHORITY Where an International preliminary examination fee as set forth in § 1.482 has been paid on the international application to the U.S. PTO: ☐ and the international preliminary examination report states that the criteria of novelty, inventive step (non-obviousness) and industrial activity, as defined in PCT Article 33(1) to (4) have been satisfied for all the claims presented in the application entering the national stage (37 C.F.R. § 1.492(a)(4)) ..... $100.00 ☐ and the above requirements are not met (37 C.F.R. § 1.492(a)(1)) ..... $710.00 ☒ U.S. PTO WAS NOT INTERNATIONAL PRELIMINARY EXAMINATION AUTHORITY Where no international preliminary examination fee as set forth in § 1.482 has been paid to the U.S. PTO, and payment of an international search fee as set forth in § 1.445(a)(2) to the U.S. PTO: ☐ has been paid (37 C.F.R. § 1.492(a)(2)) ..... $740.00 ☐ has not been paid (37 C.F.R. § 1.492(a)(3)) ..... $1040.00 ☒ where a search report on the international application has been prepared by the European Patent Office or the Japanese Patent Office (37 C.F.R. § 1.492(a)(5)) $890.00				890.00
	Total of above Calculations				= 890.00
SMALL ENTITY	Reduction by 1/2 for filing by small entity, if applicable. Assertion must be made. (note 37 C.F.R. § 1.27)				–
	Subtotal				890.00
	Total National Fee				$ 890.00
	Fee for recording the enclosed assignment document $40.00 (37 C.F.R. § 1.21(h)). (See Item 13 below). See attached "ASSIGNMENT COVER SHEET".				
TOTAL	Total Fees enclosed				$ 890.00

*See attached Preliminary Amendment Reducing the Number of Claims.

☒ Attached is a ☒ check ☐ money order in the amount of $ 890.00

☒ Authorization is hereby made to charge the amount of $ 0

☒ to Deposit Account No. 06-0308

☐ to Credit card as shown on the attached credit card information authorization form PTO-2038.

WARNING:** *Credit card information should* ***not *be included on this form as it may become public.*

☒ Charge any additional fees required by this paper or credit any overpayment in the manner authorized above.

A duplicate of this paper is attached.

***WARNING:** *"To avoid abandonment of the application the applicant shall furnish to the United States Patent and Trademark Office not later than the expiration of 30 months from the priority date: * * * (2) the basic national fee (see § 1.492(a)). The 30-month time limit may not be extended." 37 C.F.R. § 1.495(b).*

***WARNING:** *If the translation of the international application and/or the oath or declaration have not been submitted by the applicant within thirty (30) months from the priority date, such requirements may be met within a time period set by the Office. 37 C.F.R. § 1.495(b)(2). The payment of the surcharge set forth in § 1.492(e) is required as a condition for accepting the oath or declaration later than thirty (30) months after the priority date. The payment of the processing fee set forth in § 1.492(f) is required for acceptance of an English translation later than thirty (30) months after the priority date. Failure to comply with these requirements will result in abandonment of the application. The provisions of § 1.136 apply to the period which is set. Notice of Jan. 3, 1993, 1147 O.G. 29 to 40.*

☐ **Assertion of Small Entity Status**

☐ **Applicant hereby asserts status as a small entity under 37 C.F.R. § 1.27.**

NOTE: 37 C.F.R. § 1.27(c) deals with the assertion of small entity status, whether by a written specific declaration thereof or by payment as a small entity of the basic filing fee or the fee for the entry into the national phase as states:

"(c) Assertion of small entity status. Any party (person, small business concern or nonprofit organization) should make a determination, pursuant to paragraph (f) of this section, of entitlement to be accorded small entity status based on the definitions set forth in paragraph (a) of this section, and must, in order to establish small entity status for the purpose of paying small entity fees, actually make an assertion of entitlement to small entity status, in the manner set forth in paragraphs (c)(1) or (c)(3) of this section, in the application or patent in which such small entity fees are to be paid.

(1) Assertion by writing. Small entity status may be established by a written assertion of entitlement to small entity status. A written assertion must:

(i) Be clearly identifiable;

(ii) Be signed (see paragraph (c)(2) of this section); and

(iii) Convey the concept of entitlement to small entity status, such as by stating that applicant is a small entity, or that small entity status is entitled to be asserted for the application or patent. While no specific words or wording are required to assert small entity status, the intent to assert small entity status must be clearly indicated in order to comply with the assertion requirement.

(2) Parties who can sign and file the written assertion. The written assertion can be signed by:

(i) One of the parties identified in §§ 1.33(b) (e.g., an attorney or agent registered with the Office), §§ 3.73(b) of this chapter notwithstanding, who can also file the written assertion;

(ii) At least one of the individuals identified as an inventor (even though a §§ 1.63 executed oath or declaration has not been submitted), notwithstanding §§ 1.33(b)(4), who can also file the written assertion pursuant to the exception under §§ 1.33(b) of this part; or

(iii) An assignee of an undivided part interest, notwithstanding §§ 1.33(b)(3) and 3.73(b) of this chapter, but the partial assignee cannot file the assertion without resort to a party identified under §§ 1.33(b) of this part.

(3) Assertion by payment of the small entity basic filing or basic national fee. The payment, by any party, of the exact amount of one of the small entity basic filing fees set forth in §§ 1.16(a), (f), (g), (h), or (k), or one of the small entity basic national fees set forth in §§ 1.492(a)(1), (a)(2), (a)(3), (a)(4), or (a)(5), will be treated as a written assertion of entitlement to small entity status even if the type of basic filing or basic national fee is inadvertently selected in error.

(i) If the Office accords small entity status based on payment of a small entity basic filing or basic national fee under paragraph (c)(3) of this section that is not applicable to that application, any balance of the small entity fee that is applicable to that application will be due along with the appropriate surcharge set forth in §§ 1.16(e), or §§ 1.16(l).

(ii) The payment of any small entity fee other than those set forth in paragraph (c)(3) of this section (whether in the exact fee amount or not) will not be treated as a written assertion of entitlement to small entity status and will not be sufficient to establish small entity status in an application or a patent."

3. ☒ A copy of the International application as filed (35 U.S.C. § 371(c)(2)):

NOTE: Section 1.495 (b) was amended to require that the basic national fee and a copy of the international application must be filed with the Office by 30 months from the priority date to avoid abandonment. "The International Bureau normally provides the copy of the international application to the Office in accordance with PCT Article 20. At the same time, the International Bureau notifies applicant of the communication to the Office. In accordance with PCT Rule 47.1, that notice shall be accepted by all designated offices as conclusive evidence that the communication has duly taken place. Thus, if the applicant desires to enter the national stage, the applicant normally need only check to be sure the notice from the International Bureau has been received and then pay the basic national fee by 30 months from the priority date." Notice of Jan. 7, 1993, 1147 O.G. 29 to 40, at 35-36. See item 14c below.

a. ☒ is transmitted herewith.

b. ☐ is not required, as the application was filed with the United States Receiving Office.

c. ☐ has been transmitted

i. ☐ by the International Bureau.

Date of mailing of the application (from form PCT/1B/308):

_____.

ii. ☐ by applicant on _____. *(Date)*

4. ☒ A translation of the International application into the English language (35 U.S.C. § 371(c)(2)):

a. ☒ is transmitted herewith.

b. ☐ is not required as the application was filed in English.

c. ☐ was previously transmitted by applicant on _____. *(Date)*

d. ☐ will follow.

5. ☒ Amendments to the claims of the International application under PCT Article 19 (35 U.S.C. § 371(c)(3)):

NOTE: The Notice of January 7, 1993 points out that 37 C.F.R. § 1.495(a) was amended to clarify the existing and continuing practice that PCT Article 19 amendments must be submitted by 30 months from the priority date and this deadline may not be extended. The Notice further advises that: "The failure to do so will not result in loss of the subject matter of the PCT Article 19 amendments. Applicant may submit that subject matter in a preliminary amendment filed under section 1.121. In many cases, filing an amendment under section 1.121 is preferable since grammatical or idiomatic errors may be corrected." 1147 O.G. 29-40, at 36.

a. ☐ are transmitted herewith.

b. ☐ have been transmitted

i. ☐ by the International Bureau.

Date of mailing of the amendment (from form PCT/1B/308):

_____.

ii. ☐ by applicant on _____. *(Date)*

c. ☒ have not been transmitted as

i. ☒ applicant chose not to make amendments under PCT Article 19. Date of mailing of Search Report (from form PCT/ISA/210.):

November 16, 2000.

ii. ☐ the time limit for the submission of amendments has not yet expired. The amendments or a statement that amendments have not been made will be transmitted before the expiration of the time limit under PCT Rule 46.1.

6. ☒ A translation of the amendments to the claims under PCT Article 19 (38 U.S.C. § 371(c)(3)):

a. ☐ is transmitted herewith.

b. ☐ is not required as the amendments were made in the English language.

c. ☒ has not been transmitted for reasons indicated at point 5(c) above.

7. ☒ A copy of the international examination report (PCT/IPEA/409)

☒ is transmitted herewith.

☐ is not required as the application was filed with the United States Receiving Office.

8. ☒ Annex(es) to the international preliminary examination report

a. ☒ is/are transmitted herewith.

b. ☐ is/are not required as the application was filed with the United States Receiving Office.

9. ☒ A translation of the annexes to the international preliminary examination report

a. ☒ is transmitted herewith.

b. ☐ is not required as the annexes are in the English language.

10. ☒ An oath or declaration of the inventor (35 U.S.C. § 371(c)(4)) complying with 35 U.S.C. § 115
    a. ☐ was previously submitted by applicant on _____. *(Date)*
    b. ☐ is submitted herewith, and such oath or declaration
        i. ☐ is attached to the application.
        ii. ☐ identifies the application and any amendments under PCT Article 19 that were transmitted as stated in points 3(b) or 3(c) and 5(b); and states that they were reviewed by the inventor as required by 37 C.F.R. § 1.70.
    c. ☒ will follow.

II. Other document(s) or information included:

11. ☒ An International Search Report (PCT/ISA/210) or Declaration under PCT Article 17(2)(a):
    a. ☒ is transmitted herewith.
    b. ☐ has been transmitted by the International Bureau.
        Date of mailing (from form PCT/IB/308): _____.
    c. ☐ is not required, as the application was searched by the United States International Searching Authority.
    d. ☐ will be transmitted promptly upon request.
    e. ☐ has been submitted by applicant on _____. *(Date)*
12. ☒ An Information Disclosure Statement under 37 C.F.R. §§ 1.97 and 1.98:
    a. ☒ is transmitted herewith.

    Also transmitted herewith is/are:
        ☒ Form PTO-1449 (PTO/SB/08A and 08B).
        ☒ Copies of citations listed.
    b. ☐ will be transmitted within THREE MONTHS of the date of submission of requirements under 35 U.S.C. § 371(c).
    c. ☐ was previously submitted by applicant on _____. *(Date)*
13. ☐ An assignment document is transmitted herewith for recording.

    A separate ☐ "COVER SHEET FOR ASSIGNMENT (DOCUMENT) ACCOMPANYING NEW PATENT APPLICATION" or ☐ FORM PTO 1595 is also attached.

14. ☒ Additional documents:

a. ☒ Copy of request (PCT/RO/101)

b. ☒ International Publication No. WO/01/07035 A1

i. ☒ Specification, claims and drawing

ii. ☐ Front page only

c. ☒ Preliminary amendment (37 C.F.R. § 1.121)

d. ☒ Other

PCT/IB/308; PCT/IB/301; PCT/IB/304; PCT/IB/332

15. ☒ The above checked items are being transmitted

a. ☒ before 30 months from any claimed priority date.

b. ☐ after 30 months.

16. ☐ Certain requirements under 35 U.S.C. § 371 were previously submitted by the applicant on _____, namely:

AUTHORIZATION TO CHARGE ADDITIONAL FEES

WARNING: *Accurately count claims, especially multiple dependant claims, to avoid unexpected high charges if extra claims are authorized.*

NOTE: *"A written request may be submitted in an application that is an authorization to treat any concurrent or future reply, requiring a petition for an extension of time under this paragraph for its timely submission, as incorporating a petition for extension of time for the appropriate length of time. An authorization to charge all required fees, fees under § 1.17, or all required extension of time fees will be treated as a constructive petition for an extension of time in any concurrent or future reply requiring a petition for an extension of time under this paragraph for its timely submission. Submission of the fee set forth in § 1.17(a) will also be treated as a constructive petition for an extension of time in any concurrent reply requiring a petition for an extension of time under this paragraph for its timely submission." 37 C.F.R. § 1.136(a)(3).*

NOTE: *"Amounts of twenty-five dollars or less will not be returned unless specifically requested within a reasonable time, nor will the payer be notified of such amounts; amounts over twenty-five dollars may be returned by check or, if requested, by credit to a deposit account." 37 C.F.R. § 1.26(a).*

☒ Please charge, in the manner authorized above, the following additional fees that may be required by this paper and during the entire pendency of this application:

☒ 37 C.F.R. § 1.492(a)(1), (2), (3), and (4) (filing fees)

WARNING: *Because failure to pay the national fee within 30 months without extension (37 C.F.R. § 1.495(b)(2)) results in abandonment of the application, it would be best to always check the above box.*

☐ 37 C.F.R. § 1.492(b), (c) and (d) (presentation of extra claims)

NOTE: Because additional fees for excess or multiple dependent claims not paid on filing or on later presentation must only be paid or these claims cancelled by amendment prior to the expiration of the time period set for response by the PTO in any notice of fee deficiency (37 C.F.R. § 1.492(d)), it might be best not to authorize the PTO to charge additional claim fees, except possible when dealing with amendments after final action.

☒ 37 C.F.R. § 1.17 (application processing fees)

☒ 37 C.F.R. § 1.17(a)(1)–(5) (extension fees pursuant to § 1.136(a).

☐ 37 C.F.R. § 1.18 (issue fee at or before mailing of Notice of Allowance, pursuant to 37 C.F.R. § 1.311(b))

NOTE: Where an authorization to charge the issue fee to a deposit account has been filed before the mailing of a Notice of Allowance, the issue fee will be automatically charged to the deposit account at the time of mailing the notice of allowance. 37 C.F.R. § 1.311(b).

NOTE: 37 C.F.R. § 1.28(b) requires "Notification of any change in loss of entitlement to small entity status must be filed in the application . . . prior to paying, or at the time of paying . . . issue fee." From the wording of 37 C.F.R. § 1.28(b): (a) notification of change of status must be made even if the fee is paid as "other than a small entity" and (b) no notification is required if the change is to another small entity.

☐ 37 C.F.R. § 1.492(e) and (f) (surcharge fees for filing the declaration and/or filing an English translation of an International Application later than 30 months after the priority date).

SIGNATURE OF PRACTITIONER

Reg. No.: 33,961

Scott A. McCollister

(type or print name of practitioner)

Tel. No.: (216) 861-5582

Fay, Sharpe, Fagan, Minnich & McKee, LLP

Customer No.:

P.O. Address
1100 Superior Avenue, Seventh Floor
Cleveland, Ohio 44114-2518

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF	:	RAPP, Horst et al.
FOR	:	**USE OF TOSYLCHLORAMIDE(S) FOR TREATING DISEASES OF THE SKIN, MUCOUS MEMBRANES, ORGANS AND TISSUES**
SERIAL NO.	:	Unknown
FILED	:	Herewith
ATTORNEY DOCKET NO.	:	HMN 2 0021

Cleveland, Ohio 44114-2518
January 23, 2002

PRELIMINARY AMENDMENT

Assistant Commissioner For Patents
Washington, D.C. 20231

Dear Sir:

Prior to calculation of the filing fee and substantive examination of the above-referenced patent application, Applicants respectfully request amendment of the application as follows. A clean copy of the claims appears below and a marked-up version is attached as an appendix.

IN THE CLAIMS:

1. (Amended) Use of tosylchloramide(s), tosylchloramide salt(s), their derivatives and/or decomposition products for manufacture of medicaments to treat diseases of the skin and mucous membranes as well as organs and tissues, except for treatment of retroviral-(HIV)-diseases and disinfection.

4. (Amended) Use according to Claim 1, characterized in that the diseases and/or efflorescenses may be caused by microorganisms and/or accompanied by microorganisms.

5. (Amended) Use according to Claim 1, characterized in that the diseases constitute parasitic diseases, in particular scabies, pediculosis or creeping eruption.

6. (Amended) Use according to Claim 1, characterized in that the diseases affect:

a) the eye, in particular the lid, conjunctiva or cornea of the eye;
b) the ear, in particular the exterior of the ear;
c) the nose, in particular the nasal cavity;
d) the lips and mucous membranes of the mouth and/or the tongue;
e) the vulva and/or vagina;
f) the penis, in particular the glans penis and the prepuce;
g) the anus;
h) the nail, in particular the body of the nail, the wall and fold of the nail as well as the root of the nail;
i) the hair, in particular the hair follicles and the sebaceous glands and
j) the hands and feet, in particular the spaces between the fingers and toes.

7. (Amended) Use according to Claim 1, characterized in that the tosylchloramide(s), tosylchloramide salt(s), their derivatives and/or decomposition products are present in the employed base in an amount of approximately 0.1 to 20% by weight.

8. (Amended) Use according to Claim 1, characterized in that a tosylchloramide salt is employed, in particular chloramine T.

9. (Amended) Use according to Claim 7, characterized in that the base constitutes a liquid, semi-solid or solid, water-containing or water-free galenic preparation.

11. (Amended) Use according to Claim 9, characterized in that the base constitutes a dosed aerosol or a dosed solution.

12. (Amended) Use according to Claim 9, characterized in that the base constitutes a bath water additive.

13. (Amended) Use according to Claim 9, characterized in that the salve is an O/W- or a W/O-emulsion ointment.

14. (Amended) Use according to Claim 7, characterized in that the base is a cortisone-containing preparation, containing the tosylchloramide(s), tosylchloramide salt(s), their derivatives and/or decomposition products in an amount of approximately 0.1 to 20% by weight.

15. (Amended) Use according to Claim 9, characterized in that the base is a gel, in which are present the tosylchloramide(s), tosylchloramide salt(s), their derivatives and/or decomposition products in an amount of approximately 0.1 to 5% by weight.

16. (Amended) Use according to Claim 9, characterized in that the bath water additive is employed in form of pulverized substance or bath salt tablet or effervescent tablet, which is applied in water in a concentration of approximately 0.1 to 1% by weight.

Please add the following new claims:

17. Use according to Claim 1, characterized in that the tosylchloramide(s), tosylchloramide salt(s), their derivatives and/or decomposition products are present in the employed base in an amount of approximately 5 to 15% by weight

18. Use according to Claim 1, characterized in that the tosylchloramide(s), tosylchloramide salt(s), their derivatives and/or decomposition products are present in the employed base in an amount of approximately 8 to 12% by weight.

19. Use according to Claim 9, characterized in that the base is a gel, in which are present the tosylchloramide(s), tosylchloramide salt(s), their derivatives and/or decomposition products in an amount of approximately 0.1 to 2% by weight.

Remarks

Applicants respectfully request that the foregoing amendments be entered prior to substantive examination of the application.

Respectfully submitted,

FAY, SHARPE, FAGAN
MINNICH & McKEE, LLP

Date: January 23, 2002

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(216) 861-5582

CERTIFICATE OF MAILING

I hereby certify that this **PRELIMINARY AMENDMENT** is being deposited with the United States Postal Service as **EXPRESS MAIL** in an envelope numbered **EV 020233684 US**, addressed to Assistant Commissioner for Patents, Washington, DC 20231 on January 23, 2002.

By: Georgeen B. George

VERSION WITH MARKINGS TO SHOW CHANGES MADE

1. (Amended) Use of tosylchloramide(s), tosylchloramide salt(s), their derivatives and/or decomposition products for manufacture of medicaments to treat [treating] diseases of the skin and mucous membranes as well as organs and tissues, except for treatment of retroviral-(HIV)-diseases and disinfection.

4. (Amended) Use according to [one of Claims 1 to 3] Claim 1, characterized in that the diseases and/or efflorescenses may be caused by microorganisms and/or accompanied by microorganisms.

5. (Amended) Use according to [one of Claims 1 to 4] Claim 1, characterized in that the diseases constitute parasitic diseases, in particular scabies, pediculosis or creeping eruption.

6. (Amended) Use according to [at least one of the preceding Claims] Claim 1, characterized in that the diseases affect:

a) the eye, in particular the lid, conjunctiva or cornea of the eye;
b) the ear, in particular the exterior of the ear;
c) the nose, in particular the nasal cavity;
d) the lips and mucous membranes of the mouth and/or the tongue;
e) the vulva and/or vagina;
f) the penis, in particular the glans penis and the prepuce;
g) the anus;
h) the nail, in particular the body of the nail, the wall and fold of the nail as well as the root of the nail;
i) the hair, in particular the hair follicles and the sebaceous glands and
j) the hands and feet, in particular the spaces between the fingers and toes.

7. (Amended) Use according to [at least one of the preceding Claims] Claim 1, characterized in that the tosylchloramide(s), tosylchloramide salt(s), their derivatives and/or decomposition products are present in the employed base in an amount of approximately 0.1 to 20% by weight[, preferably approximately 5 to 15% by weight, in particular approximately 8 to 12% by weight].

8. (Amended) Use according to [at least one of the preceding Claims] Claim 1, characterized in that a tosylchloramide salt is employed, in particular chloramine T.

9. (Amended) Use according to [at least one of the preceding Claims] Claim 7, characterized in that the base constitutes a liquid, semi-solid or solid, water-containing or water-free galenic preparation.

10. (Amended) Use according to Claim 9, characterized in that the base constitutes an ointment, a gel, a cream, a paste, a suppository, such as a vaginal suppository, an adhesive bandage, a tablet, such an effervescent or vaginal tablet, or a capsule, a stick, a pulverized substance, a powder, a solution, an aerosol, a two-compartment system or a suspension, such as a shake mixture/dry suspension.

11. (Amended) Use according to Claim 9 [or 10], characterized in that the base constitutes a dosed aerosol or a dosed solution.

12. (Amended) Use according to Claim 9 [or 10], characterized in that the base constitutes a bath water additive.

13. (Amended) Use according to Claim 9 [or 10], characterized in that the salve is an O/W- or a W/O-emulsion ointment.

14. (Amended) Use according to [at least one of the preceding Claims] Claim 7, characterized in that the base is a cortisone-containing preparation, containing the tosylchloramide(s), tosylchloramide salt(s), their derivatives and/or decomposition products in an amount of approximately 0.1 to 20% by weight.

15. (Amended) Use according to Claim 9 [or 10], characterized in that the base is a gel, in which are present the tosylchloramide(s), tosylchloramide salt(s), their derivatives and/or decomposition products in an amount of approximately 0.1 to 5% by weight[, in particular approximately 0.1 to 2% by weight].

16. (Amended) Use according to Claim 9 [or 10], characterized in that the bath water additive is employed in form of pulverized substance or bath salt tablet or effervescent tablet, which is applied in water in a concentration of approximately 0.1 to 1% by weight.

Please add the following new claims:

17. Use according to Claim 1, characterized in that the tosylchloramide(s), tosylchloramide salt(s), their derivatives and/or decomposition products are present in the employed base in an amount of approximately 5 to 15% by weight.

18. Use according to Claim 1, characterized in that the tosylchloramide(s), tosylchloramide salt(s), their derivatives and/or decomposition products are present in the employed base in an amount of approximately 8 to 12% by weight.

19. Use according to Claim 9, characterized in that the base is a gel, in which are present the tosylchloramide(s), tosylchloramide salt(s), their derivatives and/or decomposition products in an amount of approximately 0.1 to 2% by weight.

Use of Tosylchloramide(s) for Treating Diseases of the Skin, Mucous Membranes, Organs and Tissues.

The invention concerns the use of tosylchloramide(s) as effective substance for treating diseases of the skin, the mucous membranes, organs and tissues.

Today, as in the past, there are numerous diseases whose treatment is only possible to a sub-ordinated extent, since appropriate drugs for treatment do not yet exist. This is true, for example, with respect to viral diseases, such as herpes simplex, herpes labialis, herpes zoster, varicella as well as other vesicle-forming skin diseases. With the exception of local anesthesia, there are currently no effective medicines which will alleviate the itching.

In addition, several viral statica against herpes are known, which, however, primarily present strong side effect. Thus, until now, neurodermitis or psoriasis are only treatable with corticoid preparations. Furthermore, several diseases, such as acne and aphthae pose treatment problems and most of the substances obtainable in pharmacies produce more or less successful results with respect to healing and rarely afford relief.

According to the state of the art, several suggestions have been submitted relative to chloramine T, the tosylchloramide-sodium salt, which is specifically employed as disinfecting means. Disclosure of DE 39 13 391 A1 relates to a disinfecting- and medicinal means, containing a combination of chloramine T only in combination with a reduction means. Said means is employed specifically for fighting fish diseases in aquariums and commercially raised fish, for disinfection of fish hatcheries and swimming pool water, but also for disinfection of wounds in humans, mammals and birds. The object, on which said teaching is based, consists of elimination of toxic side effects of chloramine T, in particular in fish. For said purpose, a reduction means is added, such as, for example, sodium thiosulfate or similar.

According to the teaching of DE 41 37 544 C2, an anti-microbial combination of effective substances is described as an antiseptic and for disinfection of skin, mucous membranes and wounds, containing a multi-substance mixture of 0.025 to 3% of an oxygen-splitting and 0.01 to 3% chlorine-splitting compound, plus urea, allantoin, panthenol and/or lactic acid. The oxygen-splitting compound may be an inorganic or organic

peroxide, hydroperoxide, a peroxy acid or its salt, whereas the chlorine-splitting compound constitutes sodium hypochlorite or tosylchloramide salt. The object of said technical teaching consists, in particular, in raising the low disinfecting effectiveness of the oxygen-splitting compounds, such as for example hydrogen peroxide, which is obtained by adding the above compounds.

The above described prior art is disadvantageous to the extent that combination preparations from different compounds must be employed, whereby the quantities and modes of effectiveness of the different components need to be adjusted to each other. Also, for all practically purposes, effective disinfection of the preparations ranks first, which is frequently combined with skin irritation. The state of the art discloses, according to WO 91/07876 A1, a remedy against retroviruses, in particular against the HIV-virus. Said means is applied onto objects, such as plastic equipment, medical instruments and similar in order to prevent transmission of infection. Moreover, utilization of a therapeutic compound against retro-viruses is also made available. Said means may contain chloramine T. The provided therapeutic compound prevents the activation of lymphocytic cells, where replication of the virus takes place, - in other words, there is no multiplication of HIV-viruses. Retro-viruses basically differ from the DNA-viruses which are to be treated according to the invention, such as, for example, the herpes viruses. Retro-viruses are encased viruses, having a diameter of 80 to 120 nm, whereby their genome comprises 2 RNA molecules, single stranded, and strand-positive oriented – with varied length between 8 to 11 kB. In addition, the genome of these viruses presents specific peculiarities, due to which there is a basic distinction between these viruses and other viruses.

Accordingly, the invention is based on the object of further developing the preparations of the initially described state of the art, so that additional treatment possibilities are made available for diseases, in particular skin- and mucous membrane diseases, which are practically free from side effect. Treatment method should be simple and be employed by means of as many application modes as possible. Moreover, treatment should have a broad spectrum of effectiveness and cover the largest possible range of diseases. There should be no restriction in the treatment with respect to a given application mode. Furthermore, the provided preparation should directly alleviate the occurring diseases and then cure them.

According to the invention, the above object is solved by the utilization of tosylchloramide(s), salts of tosylchloramide(s) and their derivatives and/or decomposition products for the treatment of diseases of the skin and mucous membranes, as well as organs and tissues, with the exception of treatment of retro-viral (HIV) diseases and disinfection.

Thus, it is possible to employ tosylchloramide, its salts, derivatives and decomposition products either individually or also in combination. The treatable diseases include, for example, viral diseases, such as herpes genitalis: the most widely spread venereal disease, herpes simplex, herpes labialis, chickenpox. zoster varicella-virus, shingles and herpes facialis: herpes zoster, itching of the skin, such as mosquito bites and also vesicle-forming skin, mucous membrane and tissue diseases, such as neurodermatitis, psoriasis, acne, aphtae, stomatitis aphthosa and stomatitis herpetica.

In a particularly preferred, specific embodiment of the invention, it is possible to treat skin and mucous membrane diseases, in particular such diseases which lead or may lead to "efflorescences". The term "efflorescences" stands for forms of morbid changes of the skin. These may be, for example, so-called primary efflorescences, which are directly caused by a disease. These are, for example: spots, nodules, superficial or more deeply located knots, tubera, tumors, swellings, skin eruptions, dilated, superficially extending blood vessels, pustulas, such as pus pustulas, blisters, cysts. So-called secondary efflorescences develop after the primary efflorescences and manifest themselves by scales, crusts, erosions, scrapings, cracks, tumors, scars, shrinkage and thickening of the skin.

By means of the inventive composition, such aspects of disease can, surprisingly, be directly alleviated and, as a rule, cured. Mitigation can, for example, consist in that the intensive itching disappears which is associated with diseases of the skin, mucous membranes, tissues or organs.

The diseases which are to be treated, presenting efflorescences or without efflorescences, may be caused by micro-organisms and/or accompanied by micro-organisms or may be due to parasitic effects. The term "micro-

organism" , within the framework of the invention, stands for both, bacteria, viruses (with the exception of retroviruses), mycetes as well as zooparasites, which are likewise included here. This includes, for example, diseases like scabies, pediculosis or creeping eruption. With the inventively employed preparation, treatment can be specifically provided to the following: a) the eye, in particular eye lid, cornea or conjunctiva of the eye; b) the ear, in particular the exterior of the ear; c) the nose, in particular the nasal cavity, d) lips and mucous membranes of the mouth, and/or the tongue; e) vulva and/or vagina; f) penis, in particular the glans penis and the prepuce; g) anus; h) nails, in particular the body and the wall and fold of the nail as well as root of the nail; i) hair, in particular hair follicles and sebaceous glands and j) hands and feet, in particular the spaces between fingers and toes.

According to a preferred specific embodiment of the invention, tosylchloramide salts are particularly employed as alkali and alkaline earth. Preferential employment of sodium- and calcium- as well as potash salt leads to outstanding results in treatment. Particularly preferred is sodium salt which is marketed under the trade name "chloramine T" by Synopharm of Barsbuettel (22882).

Depending upon the employed base, the active tosylchloramide ingredient is applied in the form of tosylchloramide, salt, derivative and/or decomposition product - singly or in combination -in an amount of approximately 0.1 to 20 % by weight, preferably approximately 5 to 15% by weight, specifically approximately 8 to 12% by weight. "Base" within the framework of the present invention signifies the presentation form of the preparation, which is not particularly limited according to the invention. The preparation may be liquid, semi-solid, solid, be in the form of water-containing or water-free galenical preparations, such as ointments, gels, creams, pastes, suppositories, tablets, effervescent tablets, capsules, sticks, such as lipsticks, in pulverized form, powders, solutions, adhesive bandages, aerosols, two-compartment systems or suspensions, such as for example shaking mixtures/dry suspensions.

If the base is a gel, the active tosylchloramide ingredient is present in an amount of approximately 0.1 to 5% by weight, specifically approximately 0.1 to 2% by weight. With respect to gels, these may involve hydrocarbon

gels. Hydrocarbon gels are water-free bases which distinguish themselves by appreciable chemical indifference and long keeping quality. Addition of preservatives is not required. Vaseline is preferably employed as base, its consistency can optionally be modified by solid or liquid paraffins, waxes and fatty alcohols. Hydrocarbon gels cover the treated areas of the skin in moisture-permeable fashion, resulting in the maceration of the stratum corneum. Consequently, the contained medicaments are generally able to penetrate into deeper layers of the skin. Therefore, application is indicated in the chronic stage of various dermatoses. Known bases for gels are also high-polymer polyethylenes and liquid paraffin, which differ in their melting behavior from Vaseline and which have a clearly higher dropping point.

Hydrogels are also suitable as base. Hydrogels are fat-free, washable bases, which are manufactured by gel formation of organic or inorganic auxiliary substances with high percentages of water (approximately 90 to 98%). Generally, they also contain moisturizing agents and preservatives. By way of organic gel developers, anionic compounds can be used, such as carboxy-methyl cellulose and alginate, or non-ionic macro-molecules such as methyl cellulose and hydroxy-ethyl cellulose. Such type of hydro-gels have initially a cooling effect and, after evaporation of the water, form a coating of dried-on film on the surface of the skin. In contrast thereto, with anionic poly-acrylates of the carbopol-type, hydro gels are obtained which can be rubbed into the skin and which therefore possess a certain depth effect. By neutralizing poly-acrylic acid with certain amines, alcohol-containing gels can be prepared with ethanol or isopropanol, which are capable of increasing the cooling as well as the depth effect. Hydrogels are preferably suited for treatment of neurodermatitis, psoriasis, acne, mosquito bites and apthae.

W/O emulsion ointments are preferably employed by way of ointments, such as adhesive- or eye ointments. Based on their lipophile outer phase, W/O emulsion ointments lubricate the skin and cannot be washed off with water. They contain one or several W/O emulsifiers, such as for example degras, degras alcohol, higher fatty alcohols or glycerin fatty acid ester. W/O emulsion ointments can be preserved; they frequently contain antioxidants. Their skin spreading property is excellent. In contrast to the O/W emulsions, the flow direction of the moisture of the skin is directed toward the interior of the skin under the influence of the lipophile outer phase of this type of ointment. This increases swelling and penetration. These basic characteristics are

preferably suited for dry skin.

Another suitable ointment type are the O/W-emulsion ointments. O/W-emulsion ointments (creams) can be washed off, based on their watery outer phase. They generally contain complex emulsifiers whose hydrophilic component is formed by fatty alcohol sulfates or non-ionic polyethylene-glycol containing tensides. By way of lipophile stabilizers, use is made of fatty alcohols, sorbitan fatty acid ester or glycerin fatty acid ester. O/W-emulsions frequently contain moisturizing agents and, as a rule, need to be stabilized with preservatives. Because of their watery outer phase, creams can generally be easily distributed over the skin and have a cooling effect. O/W-emulsions are used in the treatment of sub-acute and sub-chronic dermatoses and are preferably suited primarily for the seborrheic type of skin . The O/W- or W/O-emulsion ointments are particularly appropriate in the treatment of herpes simplex, herpes labialis, herpes zoster, varicells and other vesicle-forming skin diseases. The active ingredient, tosylchloramide is contained in O/W- or W/O ointments in volume of preferably 0.1 to 20% by weight, particularly preferred approximately 5 to 15% by weight and most particularly preferred approximately 8 to 12% by weight.

A particularly preferred preparation contains 10% by weight of active tosylchloramide ingredient in a cortisone-containing adhesive ointment (0.001% by weight corticoid) such as Volon A, a brand name of Messrs. Squibb-Heyden GmbH. In said preparation, the active tosylchloramide ingredient is particularly effective, preferably with herpes simplex, herpes labialis, herpes zoster, varicells and other vesicle-forming diseases of the skin, including aphthae, stomatitis aphthosa and stomatitis herpetica.

Further possible bases are solid galenic preparations, such as pulverized substances, powders or pastes, which may be employed, for example, as bath water additives for hand-, foot- or full baths, and which contain the active tosylchloramide ingredient in an amount of approximately 0.1 to 20% by weight. When employed in form of powder, for use as an additive to bath water, it preferably contains a concentration of approximately 0.1 to 1% by weight (particularly with neurodermatitis). Solid preparations further comprise suppositories or vaginal beads - which dissolve and form a foam lining, - sticks for treating areas of the lips, skin or mucous

membranes (in particular with herpes labialis), adhesive bandages, for example with tissue of natural or artificial origin, or both, either porous, or air- and moisture-tight, tablets, such as capsules of soft or hard gelatin, effervescent tablets and similar.

In addition, aerosols, such as sprays, can also be employed in gas-tight containers, which must be operated mechanically or are operated with FCKW-free propelling gas, such as spray mist, foam, gel or adhesive coating, which is generated on the areas of the skin or mucous membranes which are to be treated. Particular consideration is given in this regard to dosing aerosols or dosing solutions which release a defined volume of substance with each stroke or push. Two-component systems in gas-tight vessels may likewise be employed, in which the effective tosylchloramide substances are stored alone or with an inert carrier material and/or propellant in two separate chambers and are mixed only with each application.

The benefits related to the invention are multifold. It has been demonstrated that tosylchloramide compounds can be employed with all vesicle-forming, itching, viral-caused skin and mucous membrane diseases and lead to the same results - the same is true of corresponding diseases of tissues and organs. Not only is there attained rapid alleviation of the acute symptomatic, but as well a decline in the recidivism rate.

It is particularly surprising that the inventive employment of the active tosylchloramide ingredient leads to excellent treatment results, completely independent from the utilized base. One is not restricted to a given application mode. It is possible that already relatively low amounts of the active tosylchloramide ingredient will lead to full healing. In addition, as indicated above, the application form can be adapted to the specific requirements, so that ample variability is given with respect to presentation form.

The direct or local application, for example, in form of gels, salves, sticks or as a bath additive has the advantage that the affected location can be directly treated, that good adhesion is obtained, even with moist mucous membranes and - at the same time - it is possible to achieve long dwell and adsorption time. Of particular benefit is the galenic form of the spray, whereby with spraying on the painful or itching portions of

the skin, application of the active ingredient can take place pain-free and without contact, in contrast to application of a salve, which is something which will surely increase patient's compliance. The local application initially leads to noticeable burning after a use and then to rapid mitigation of the acute complaints - - healing of any efflorescenses occurs, as a rule, within just a few days. Treatment can already take place before development of possible efflorescenses, which are formed only in the last stage of a skin disease. It is precisely in the case of herpes that such efflorescenses are prevented through treatment, thus lending itself to preventive treatment as well.

Tosylchloramide compounds, such as chloramine T have long been known as disinfectants, which may also be employed for disinfection of drinking water and they are thus thoroughly tested with respect to their effectiveness, their elimination behavior, unwelcome effects, counter-indications, reciprocal interactions, toxicological properties, as well as mutative propensity, etc.

Therefore, the inventive applications seem to raise no inherent concern regarding compatibility upon direct contact with the skin and potential sensibilisation, such as for example the local application in appropriate concentration in combination with an ointment.

Additional properties and benefits of the present invention are apparent from the following exemplary embodiments, which are not intended to limit the invention-specific teaching. To the person skilled in the art, additional exemplary embodiments are obvious within the framework of the inventive disclosure.

Examples:

The following examples 1 - 3 demonstrate, in detail, the preparation of some inventively applied bases. After that, treatment with the active tosylchloramide ingredient is described in Examples 4 to 7.

Example 1:

Preparation of a W/O-emulsion ointment in form of a wool wax alcohol salve

The wool wax alcohol salve was composed as follows:

wool wax alcohols	6.0 parts
cetyl stearyl alcohol	0.5 parts
white Vaseline	93.5 parts

The substances were melted in a water bath and stirred until cooled. Up to 12 parts of Vaseline can be substituted by viscous paraffin. A preparation having the following composition was then prepared.

Wool wax alcohol salve	1 part
water	1 part
tosylchloramide-sodium	0.2 parts

Into the wool wax alcohol salve, which had been heated to approximately 60°C, water was incorporated that had been heated to the same temperature. The salve was stirred until cooled and the tosylchloramide-sodium was then incorporated.

Example 2

Preparation of an O/W-emulsion salve in form of a hydrophilic ointment.

The hydrophilic ointment had the following composition:

emulsifying cetyl-stearyl alcohol	30 parts
viscous paraffin	35 parts
white Vaseline	35 parts

The substances were melted in a water bath and stirred until cool. In the event that no easily spreadable

ointment is obtained according to the cited prescription, viscous paraffin and white Vaseline may be exchanged with each other, as needed, by up to 10 percent. This salve was then used to prepare the following composition:

hydrophilic salve	30 parts
water	70 parts
tosylchloramide-sodium	14 parts

The hydrophilic salve was melted in a water-bath at approximately 70°C and mixed with small portions of water that had been heated to the same temperature. The salve was stirred until cool and the evaporated water replaced. Tosylchloramide-sodium was incorporated.

Example 3:

Preparation of a hydro-gel having the following composition:

hydroxy-ethylene cellulose 300	4.5 g
glycerol 85%	30.5 g
purified water	65.5 g
tosylchloramide-sodium	2.0 g

The hydroxy-ethylene cellulose was uniformly suspended, under stirring, in the freshly boiled and cooled-down water, in which the tosylchloramide has been dissolved. The mixture had to expand until clear gel had developed. After that, glycerol was stirred in. Evaporated water was replaced, if necessary.

Example 4:

The hydrogel which had been obtained in Example 3 was applied onto mosquito bites. This resulted in rapid decline of itching. Blisters dried up within 24 to 36 hours, with healing of the skin after additional 24 to 36 hours.

Example 5:

Chloramine T was mixed into the known adhesive ointment "Volon A", which contains corticosteroids and the following treatments were undertaken:

a) Aphtha:

An ointment, containing the inventively employed tosylchloramide substance, was applied on the aphthae. Following application, there occurred a brief burning sensation, after that one barely noted any sensitivity of the treated aphthae, whereupon rapid healing took place of the ulcus within a matter of 1 to 2 days. The aphthae therapy also demonstrated that, contrary to the traditionally employed Zovirax ointment, application onto mucous membrane (mouth, region of genitalia) is possible and successful.

b) Herpes labialis:

The broken-out herpes healed off in the shortest possible time, which made itself known by means of prickling or tingling. With timely recognition, as a rule, there will not be a break-out.

c) Rhagades in the Corner of the Mouth :

The course of the treatment corresponds to what was described under "herpes labialis". Here again, notice was taken of rapid and lasting healing. Generally, with herpes infection in the oral cavity, in particular at the hard palate, one obtains excellent treatment results with the inventively employed adhesive salve.

d) Neurodermatitis with herpes superinfection:

Instant decline in the unbearable itching was attained with concurrently amazingly rapid healing of the skin. For persons suffering from neurodermatitis, the elimination of itching is of utmost importance, since it does away with the irresistible urge to scratch, which frequently leads to further worsening and further spreading of the

rash. Relief can be achieved with the inventively employed effective substance.

Example 6:

Instead of adhesive salve Volon A with added chloramine T, a normal cooling salve was prepared - "unguentum leniens" which merely contained chloramine T-powder (2% by weight) as active ingredient, but no corticoid. The success described under Example 5 was the same. The utilization of a hydrolotion containing only chloramine T as active ingredient resulted in the above represented results. Even addition of the powder to the bath water brought comparable results.

Example 7:

15 test patients with different aspects of disease were treated under control of a physician. After treatment over a period of several days, the physician made an evaluation with respect to effect and overall results of the treatment. For evaluation of effect, the following assessment grades could be assigned: "none" - "minor" - "good" - "very good" - "outstanding". For assessment of overall application results, it was possible to select from the following:

"no improvement" - "moderate improvement" - "good improvement" - "excellent improvement". The executed examinations with respective the various disease aspects and the obtained results are summarized in the Table which is shown below:

Table

Test Patient	Disease Aspect	Base	Period of Application	Evaluation of Effect	Overall Result of Application
1	herpes labialis	Adh.ointment Volon A with Chloramine T	5 days 2 times per day	very good	excellent improvement
2	herpes labialis	Adh.ointment Volon A with Chloramine T	3 days 1-3 times per day	excellent	excellent improvement
3	herpes labialis	Adh.ointment Volon A with Chloramine T	2 days 1-2 times per day	excellent	excellent improvement
4	herpes labialis	Adh.ointment Volon A with Chloramine T	6 days 1-4 times per day	good	good improvement
5	herpes labialis	Adh. ointment Volon A with Chloramine T	4 days 1-3 times per day	very good	good improvement
6	herpes labialis	Adh.ointment Volon A with Chloramine T	2 days 1-2 times per day	excellent	excellent improvement
7	Aphthae	Adh.ointment Volon A with Chloramine T	2 days 2-3 times per day	excellent	excellent improvement

Test Patient	Disease Aspect	Base	Period of Application	Evaluation of Effect	Overall Result of Application
8.	Psoriasis	Ointment with 2% by wt. of chloramine T	7 days 2-3 times per day	insignificant	moderate improvement
9	vesicles with watery liquid	ointment with 2% by wt. of chloramine T	7 days 3-4 times per day	insignificant	moderate improvement
10	psoriasis of the scalp	ointment with 2% by wt. of chloramine T	7 days 3 times per day	excellent	excellent improvement
11	lip rhagade	ointment with 2% by wt. of chloramine T	4 days 1-3 times per day	excellent	excellent improvement
12	lip rhagade	ointment with 2% by wt. of chloramine T	5 days 2 times per day	good	excellent improvement
13	stomatitis herpetica	ointment with 2% by wt. of chloramine T	5 days 1-4 times per day	excellent	excellent improvement
14	neuroderma-titis with herpes super-infection	ointment with 2% by wt. of chloramine T	6 days 1-2 times per day	excellent	excellent improvement
15	Shingles	ointment with 3% by wt. of chloramine T	20 days 1 time per day	excellent	excellent improvement

The preceding results clearly demonstrate the surprisingly high effectiveness with utilization of the

tosylchloramide compound according to the invention. Even psoriasis disappeared completely after a 7 day treatment. In just two cases of probably chronic disease aspect was it possible to achieve only moderate improvement.

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Patent Claims

1. Use of tosylchloramide(s), tosylchloramide salt(s), their derivatives and/or decomposition products for treating diseases of the skin and mucous membranes as well as organs and tissues, except for treatment of retroviral-(HIV)-diseases and disinfection.

2. Use according to Claim 1, characterized in that the diseases affect the skin and the mucous membranes.

3. Use according to Claim 2, characterized in that the diseases result or may result in efflorescenses.

4. Use according to one of Claims 1 to 3, characterized in that the diseases and/or efflorescenses may be caused by microorganisms and/or accompanied by microorganisms.

5. Use according to one of Claims 1 to 4, characterized in that the diseases constitute parasitic diseases, in particular scabies, pediculosis or creeping eruption.

6. Use according to at least one of the preceding Claims, characterized in that the diseases affect:

a) the eye, in particular the lid, conjunctiva or cornea of the eye;
b) the ear, in particular the exterior of the ear;
c) the nose, in particular the nasal cavity;
d) the lips and mucous membranes of the mouth and/or the tongue;
e) the vulva and/or vagina;
f) the penis, in particular the glans penis and the prepuce;
g) the anus;
h) the nail, in particular the body of the nail, the wall and fold of the nail as well as the root of the nail;
i) the hair, in particular the hair follicles and the sebaceous glands and
j) the hands and feet, in particular the spaces between the fingers and toes.

7. Use according to at least one of the preceding Claims, characterized in that the tosylchloramide(s), tosylchloramide salt(s), their derivatives and/or decomposition products are present in the employed base in an amount of approximately 0.1 to 20% by weight, preferably approximately 5 to 15% by weight, in particular approximately 8 to 12% by weight.

8. Use according to at least one of the preceding Claims, characterized in that a tosylchloramide salt is employed, in particular chloramine T.

9. Use according to at least one of the preceding Claims, characterized in that the base constitutes a liquid, semi-solid or solid, water-containing or water-free galenic preparation.

10. Use according to Claim 9, characterized in that the base constitutes an ointment, a gel, a cream, a paste, a suppository, such as a vaginal suppository, an adhesive bandage, a tablet, such an effervescent or vaginal tablet, or a capsule, a stick,a pulverized substance, a powder, a solution, an aerosol, a two-compartment system or a suspension, such as a shake mixture/dry suspension.

11. Use according to Claim 9 or 10, characterized in that the base constitutes a dosed aerosol or a dosed solution.

12. Use according to Claim 9 or 10, characterized in that the base constitutes a bath water additive.

13. Use according to Claim 9 or 10, characterized in that the salve is an O/W- or a W/O-emulsion ointment.

14. Use according to at least one of the preceding Claims, characterized in that the base is a cortisone-containing preparation, containing the tosylchloramide(s), tosylchloramide salt(s), their derivatives and/or decomposition products in an amount of approximately 0.1 to 20% by weight.

15. Use according to Claim 9 or 10, characterized in that the base is a gel, in which are present the tosylchloramide(s), tosylchloramide salt(s), their derivatives and/or decomposition products in an amount of approximately 0.1 to 5% by weight, in particular approximately 0.1 to 2% by weight.

16. Use according to Claim 9 or 10, characterized in that the bath water additive is employed in form of pulverized substance or bath salt tablet or effervescent tablet, which is applied in water in a concentration of approximately 0.1 to 1% by weight.

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Zur Erklärung der Zweibuchstaben-Codes, und der anderen Abkürzungen wird auf die Erklärungen ("Guidance Notes on Codes and Abbreviations") am Anfang jeder regulären Ausgabe der PCT-Gazette verwiesen.

(54) Title: USE OF TOSYLCHLORAMIDE(S) FOR TREATING DISEASES OF THE SKIN, MUCOUS MEMBRANES, ORGANS AND TISSUES

(54) Bezeichnung: VERWENDUNG VON TOSYLCHLORAMID(EN) ZUR BEHANDLUNG VON ERKRANKUNGEN DER HAUT, DER SCHLEIMHAUT, VON ORGANEN UND GEWEBEN

(57) Abstract: The invention concerns the use of tosylchloramide(s), tosylchloramide salt(s), their derivatives and/or the decomposition products for treating diseases of the skin, mucous membranes, organs and tissues, excluding treatment of retroviral diseases (HIV) and disinfecting processes. It has been shown that tosylchloramide compounds can be used even for all diseases of the skin and viral mucosa causing formation of vesicles and itching, and they can lead to similar results as those obtained when they are used to treat corresponding diseases in tissues and organs. They not only provide quick relief of the acute symptoms and cure, but they also reduce frequency of recurrence. The inventive use is characterised in that it leads to very good treatment results, entirely independently of the form of preparation used, and it does not have to be administered in one specific manner. Relatively low amounts of tosylchloramide active principle can provide complete cure.

(57) Zusammenfassung: Die Erfindung betrifft die Verwendung von Tosylchloramid(en), Tosylchloramidsalz(en), deren Derivaten und/oder Abbauprodukten zur Behandlung von Erkrankungen der Haut, der Schleimhaut, von Organen und Geweben, ausgenommen die Behandlung von Retrovirus-(HIV)-Erkrankungen und Desinfektionen. So hat sich gezeigt, dass Tosylchloramid-Verbindungen auch bei allen bläschenbildenden, juckenden, viral bedingten Haut- und Schleimhauterkrankungen einsetzbar sind, und zu denselben Erfolgen führen, wie auch bei entsprechenden Erkrankungen an Geweben und Organen. Es wird nicht nur eine schnelle Linderung der akuten Sympotomatik und Heilung, sondern auch eine Abnahme der Rezidivhäufigkeit erzielt. Besonders überraschend ist, dass die erfindungsgemässe Verwendung völlig unabhängig von der eingesetzten Grundlage zu einem sehr guten Behandlungsergebnis führt, es liegt keine Festlegung auf einen bestimmten Verabreichungsweg vor. Hierbei können bereits relativ geringe Mengen des Tosylchloramid-Wirkstoffs zu einer vollständigen Abheilung führen.

WO 01/07035 A1

Attorney Docket No. HMN 2 0021

DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION

As a below inventor, I hereby declare that:
My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor(if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

USE OF TOSYLCHLORAMIDE(S) FOR TREATING DISEASES OF THE SKIN, MUCOUS MEMBRANES, ORGANS AND TISSUES

the specification of which
[ ] is attached hereto

[X] was filed on January 23, 2002
Application Serial No. 10/031,851
and was amended on January 23, 2002.

[ ] was filed as PCT on

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, 1.56 (a).

I hereby claim foreign priority benefits under Title 35, United States Code, 119 or 365(b) of any foreign application(s) for patent or inventor□s certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed above and have also identified below, by check the box, any foreign application(s) for patent or inventor□s certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed:

Prior Foreign Application			
DE 199 34 585.6	Germany	23/July/1999	
(Number)	(Country)	(Day/Month/Year Filed)	Certified Copy Attached?

I hereby claim the benefit under 35 U.S.C. 119(e) of any United States provisional application(s) listed below.

	[ ]additional provisional application numbers are
Application No(s)(Day/Month/Year Filed)	listed on a supplemental priority data sheet attached

I hereby claim the benefit under Title 35, United States, 120 of any United States application(s) or any PCT international application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application or PCT International application in the manner provided by the first paragraph of Title 35, United States Code, 112, I acknowledge the duty to disclose material information which is material to patentability as defined in Title 37, of Federal Regulations Code, 1.56(a) which became available between the filing date of the prior application and the national or PCT international filing date of this application:

PCT/EP00/06997	July 21, 2000	
U.S. Parent Application or PCT Parent Number	Parent Filing Date (MM/DD/YYYY)	Parent Patent Number (If Applicable)

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POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

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